

Docket No. AB-135U

Remarks

Applicant has herein amended claims 1, 6, 23-25, 27-30 and 32, and has canceled claims 7-15, 26, 31 and 33. Twenty one (21) claims remain pending in the application: claims 1-6, 16-25, 27-30 and 32, of which claims 1 and 6 are independent. Applicant respectfully requests reconsideration of the pending claims, in view of the amendments above and comments below.

Double Patenting

On page 2 of the Office Action mailed December 3, 2003, claims 1-3, 5-25, 27-30, 32 and 33 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 21, 1, 4-8, 10-21, 23-25, 27-30, 34 and 35 respectively of copending Application No. 09/993085. The Office action states:

"a method of treating patients with eating disorders" as opposed to "a method of preventing diabetes" and "modulate" as opposed to "inhibit" are considered functionally equivalent.

Although the applicant disagrees with the Examiner's conclusion that the claims "are not patentably distinct from each other," applicant has enclosed herewith a terminal disclaimer to address this rejection. Thus, without necessarily agreeing with such rejection but in order to speed the prosecution of the present application to issuance, applicant has filed herewith a terminal disclaimer showing the cited application is commonly owned with the present application, thereby overcoming the subject rejection.

Claim Rejections - 35 USC § 103

On page 3 of the Office action, claims 6, 16-19 and 21 were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Rise US-5782798 in view of Fischell US-6006124, and on page 4 of the Office action, claims 1-4, 7 and 8 were rejected under

Appl. Ser. No. 09/993,086
Amendment A dated March 25, 2004
Reply to Office action of December 3, 2003

Page 6 of 11

Docket No. AB-135U

35 U.S.C. 103(a) as unpatentable (obvious) over Rise in view of Fischell as applied to claim 6 above and further in view of Frankish et al (Neuropeptide Y, the Hypothalamus, and Diabetes: Insights into the Central Control of Metabolism - article). The Office Action states that:

Rise....delivers electrical stimulation and therapeutic dosages of one or more drugs to the lateral hypothalamus; paraventricular nucleus or the ventral medial hypothalamus.... *Office action, paragraph 3.*

Frankish et al teaches...that significantly higher NPY concentrations exist in the arcuate nucleus, paraventricular nucleus and the dorsal medial nucleus. *Office action, paragraph 4.*

Each of these claims, or a claim from which they depend, has been amended or canceled, as described below.

To overcome these rejections, applicant has amended independent claims 1 and 6, and believes that Rise, nor Frankish, nor any prior art known to the applicant, alone or in combination, discloses the invention as claimed in amended independent claims 1 and 6.

For instance, and as stated by the Examiner, Rise teaches only electrical stimulation or drug infusion into the lateral hypothalamus, paraventricular hypothalamus, and ventral medial hypothalamus (see Table I in column 3, Table II in column 4 and Table IV in column 5).

However, independent claims 1 and 6, as amended, address a portion of the brainstem known as the nucleus of the solitary tract. See, *inter alia*, original claims 1 and 6 and paragraphs [0109] and [0110] of the present application:

[0109] According to some embodiments of the invention, the electrical and/or drug stimulation increases excitement of one or more of those areas of the brain that exhibit chronic decreased activity in patients with eating disorders relative to control subjects, thereby treating or preventing eating disorders and the symptoms and pathological consequences thereof....For example, for patients suffering from obesity and/or the like, this excitatory stimulation may be applied to...the nucleus of the solitary tract 110....

Docket No. AB-135U

[0110] According to other embodiments of the invention, the electrical and/or drug stimulation decreases excitement of one or more of those areas of the brain that exhibit chronic *increased* activity in patients with eating disorders relative to control subjects, thereby treating or preventing eating disorders....For example,...for patients suffering from anorexia or the like, this inhibitory stimulation may be applied to...the nucleus of the solitary tract 110.

Rise does not mention stimulation of the nucleus of the solitary tract, or indeed, any area of the brainstem. Thus, applicant has amended Independent claims 1 and 6 to retain only the nucleus of the solitary tract, while the other areas claimed in original independent claims 1 and 6 have been removed by the present amendment. As a result of these amendments, claims 7-15 have been canceled.

As Rise and the other known prior art do not mention stimulation of the nucleus of the solitary tract or *any area of the brainstem*, it is believed that independent claims 1 and 6 have been placed in condition for allowance. Acknowledgment of the same is earnestly solicited.

On page 3 of the Office action mailed December 3, 2003, claims 16-19 and 21, which depend from claim 6, were also rejected as obvious over Rise in view of Fischell. As each of these claims depends directly from independent claim 6, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 6.

On page 4 of the Office action, claims 2-4, 7 and 8, which depend from claim 1, were also rejected as obvious over Rise in view of Fischell and further in view of Frankish et al. For claims 2-4, which each depend directly from independent claim 1, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 1. Without necessarily agreeing with the rejection, but in order to speed the prosecution of the present application to issuance, applicant has canceled claims 7 and 8,

Appl. Ser. No. 09/993,086
Amendment A dated March 25, 2004
Reply to Office action of December 3, 2003

Page 8 of 11

Docket No. AB-135U

as mentioned earlier, making the rejection thereto moot. Applicant reserves the right to pursue the canceled claims in a continuing application(s).

On page 5 of the Office action, claims 9, 10 and 12-15 were rejected as obvious over Rise in view of Fischell as applied to claim 6, and further in view of Mondai et al (Orexins (Hypocretins): Novel Hypothalamic Peptides with Divergent Functions - article). Without necessarily agreeing with the rejection, but in order to speed the prosecution of the present application to issuance, applicant has canceled claims 9, 10 and 12-15, as mentioned earlier, making the rejection thereto moot. Applicant reserves the right to pursue the canceled claims in a continuing application(s).

On page 6 of the Office action, claim 11 was rejected as obvious over Rise in view of Fischell as applied to claim 6, and further in view of Bernfield et al US-6284729. Without necessarily agreeing with the rejection, but in order to speed the prosecution of the present application to issuance, applicant has canceled claim 11, as mentioned earlier, making the rejection thereto moot. Applicant reserves the right to pursue the canceled claim in a continuing application(s).

Also on page 6 of the Office action, claims 20 and 23-32 were rejected as obvious over Rise in view of Fischell as applied to claim 6, and further in view of Zabara US-5540734. For claim 20, which depends directly from independent claim 6, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 6. For claims 23-25, 27-30 and 31, which, after entry of this amendment, depend directly or indirectly from independent claim 1, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 1. Without necessarily agreeing with the rejection, but in order to speed the prosecution of the

Appl. Ser. No. 09/993,086
Amendment A dated March 25, 2004
Reply to Office action of December 3, 2003

Page 9 of 11

Docket No. AB-135U

present application to issuance, applicant has canceled claims 26 and 31, as mentioned earlier, making the rejection thereto moot. Applicant reserves the right to pursue the canceled claims in a continuing application(s).

On page 7 of the Office action, claim 5 was rejected as obvious over Rise in view of Fischell and Frankish as applied to claim 1 and further in view of Schulman et al US-5193540. As this claim depends directly from independent claim 1, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 1.

Also on page 7 of the Office action, claim 22 was rejected as obvious over Rise in view of Fischell as applied to claim 6 and further in view of Schulman et al. As this claim depends directly from independent claim 6, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 6.

On page 8 of the Office action, claim 33 was rejected as obvious over Rise in view of Fischell and Zabara US-5540764 as applied to claim 23, and further in view of Schulman et al. Without necessarily agreeing with the rejection, but in order to speed the prosecution of the present application to issuance, applicant has canceled claims 33, as mentioned earlier, making the rejection thereto moot. Applicant reserves the right to pursue the canceled claim in a continuing application(s).

Conclusion

After entry of this amendment, all pending claims depend directly or indirectly from amended independent claim 1 or 6. As such, applicants respectfully request consideration of amended independent claims 1 and 6, and their dependent claims, in light of these remarks and

Appl. Ser. No. 09/993,086
Amendment A dated March 25, 2004
Reply to Office action of December 3, 2003

Page 10 of 11

Docket No. AB-135U

the related claim amendments. Entry of the changes to the claims and indication of allowance relative to all of pending claims (claims 1-6, 16-25, 27-30 and 32) is earnestly solicited.

The Examiner is invited to telephone the undersigned, Laura H. Bishop, at his convenience should any issues remain after consideration and entry of this response, in order to permit early resolution of the same.

Respectfully Submitted,


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March 25, 2004
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Appl. Ser. No. 09/993,086
Amendment A dated March 25, 2004
Reply to Office action of December 3, 2003

Page 11 of 11